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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/435,576 11/08/99 CHEN

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EXAMINER

WILLIAMSON, M

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 04/25/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/435,576

Applicant(s)

CHEN et al.

Examiner

Williamson

Group Art Unit

1616

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 3/9/01
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-75 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-75 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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## DETAILED ACTION

### *Pending Claims*

The pending claims in the instant application are 1 -75. The independent claims are 1, 48, 51, 58, 62, 70-72 and 74.

### *Claim Rejections - 35 USC § 112*

1. The rejection of claims 1-75 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a controlled release oral solid dosage form comprising a core of an alkyl ester of a hydroxy substituted naphthalene compound, a pharmaceutically acceptable , water swellable polymer and an osmotic agent and an outer coating layer which completely covers the core comprising a pH sensitive coating agent and a water insoluble polymer used at a weight ratio of about 0.1:1 to 0.75:1 at a combined coating weight of 0.5-5% by weight, does not reasonably provide enablement for a controlled release oral solid dosage formulation without the recited limitations regarding a core and an outer coating having the weight ratio and combined coating weight has been maintained for reasons of record in paper number 2, paragraph 2.

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*Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monaghan et al. (U.S. Patent 4,231,938) in view of Oshlack et al. (U.S. Patent 5,324,351 or 5,472,712).

Monaghan et al. discloses an alkyl ester of a hydroxy substituted naphthalene derivative, lovastatin, which is a highly active hypocholesteremic and hypolipemic medicament that may be administered orally or parentally in the form of capsule, a tablet, an injectionable preparation and the like in amount with a range of from about 2 mg. to 2000 mg. which may varied based on age, severity, body weight and other conditions of human patients. Monaghan et al. does not disclose the structure of the capsule, tablet, etc.

Oshlack et al. discloses compositions used to overcoat active agent including pharmaceuticals (see Abstract and entire document). The advantage of the overcoat is

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to protect from the environment. Therefore, it would have been obvious to one of ordinary skill in the art to use the coating compositions disclosed by Oshlack et al. in the invention of Monaghan et al. to obtain an active ingredient that is protected from the environment to provide stability in the absence of a factual showing to the contrary or a showing of unexpected result.

#### *Double Patenting*

4. The rejection of claims 1-75 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 5,916,595 has been withdrawn in view of Applicant's submission of a Terminal Disclaimer.

#### *Response to Arguments*

5. Applicant's arguments filed March 9, 2001 have been fully considered but they are not persuasive.

Applicant argues that support for the claimed limitation recited can be found through the specification (see Response, page 2). Applicant also states in the specification that other means can be used to meet the limitations of the instant claimed

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invention (see page 19, line 38 to page 20, line 6). It is therefore the Examiner's position that the instant claimed invention does not distinguish over that which is known in the art.

6.

### **Crystal Mall 1 Facsimile Center**

A facsimile center has been established in Crystal Mall 1, room 7C10. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 308-4556. The new location should be used in all instances when faxing any correspondence to Group 1600. Use of the new Crystal Mall 1 center will facilitate rapid delivery of materials to the Group. The faxing of all papers must conform with the notice published in the Official Gazette, 1096 O.G. 30 (November 15, 1989).

7. Any inquiry concerning this communication or earlier communication from the examiner should be directed to Michael A. Williamson whose telephone number is (703) 308-1235.



Michael A. Williamson  
Patent Examiner  
Group 1610

Williamson010422  
April 23, 2001